Remarks/Arguments

Examiner and applicant's representative conducted a telephonic interview on September 3, 2009. The limitations of the Shin and Saidara references were discussed as well as the objective evidence of non-obviousness cited by applicant's representative. Examiner suggested explicitly including language from paragraph 48 into independent claims 1 and 25, as well as adding the element of a processor to claim 13.

Examiner rejects claims 1-4, 7-16, and 31-36 under 35 U.S.C. 103(a) as being unpatentable over Saidara (US 2005/0038332) in view of Shin (US 2005/0004439). Examiner rejects claims 5, 6, 17, 18, 29, and 30 under 35 U.S.C 103(a) as being unpatentable over Saidara in view of Shin and in further view of Glukhovsky (US 7,200,253). Applicant respectfully traverses the rejections.

The Manual of Patent Examining Procedure, Section 2111.01 part IV, states that the applicant may act as their own lexicographer "by clearly setting forth a definition of the term that is different from its ordinary and customary meaning(s)." Applicant defines the terms "threshold profile," "blood glucose notification threshold profile," and "blood glucose threshold profile" in paragraph [0048] of applicant's specification:

> The terms "threshold profile" (TP), "blood glucose notification threshold profile" and "blood glucose threshold profile" as used herein mean a pair of functions comprising upper and lower blood glucose notification thresholds as functions of time. The upper and lower BGC *[blood glucose concentration]* notification threshold functions are the upper and lower bounds of an expected BGC range. The upper and lower blood glucose

notification threshold functions may be conveniently visualized as graphs, or curves, of glucose concentration versus time. (emphasis added)

The limitations of the Saidara reference (US 2005/0038332) were discussed in the response (filed April 30, 2009) to the office action of March 3, 2009 and will not be repeated here.

The thresholds discussed by Shin differ from the threshold profiles of the applicant in four significant ways:

1. Shin's thresholds are based upon first and second derivatives.
2. Shin's thresholds do not appear to be continuous.
3. Shin's thresholds are a function of glucose level.
4. Shin's thresholds are a function of current blood glucose concentration measurements.

In paragraphs [0018-0020] Shin states: "…the first parameter relating to the first data value may be a second-order derivative…." and "The first parameter relating to the first data value may also be a first-order derivative…." and "terminating receipt of data from the sensor when the first parameter relating to the first data value exceeds the first threshold value,…" In paragraph [0021] Shin states: "Terminating receipt of data from the sensor may occur when the first parameter relating to the second data value exceeds the first threshold value…" Throughout paragraphs [0018-0021] Shin describes thresholds based upon first and second-order derivatives. Further support may be found in paragraphs [0161, 0162, and 0164].

In paragraph [0012] of applicant's specification applicant states: "For the sake of clarity, it is worthwhile to distinguish between a BGC threshold that may change

continuously over time, which is not disclosed in the art, and a threshold for a rate of change of BGC, which is disclosed in the art." Further, in paragraph [0083] applicant states: "…the art enhancements meant to address this inadequacy, such as notification thresholds based on the rate of change of BGC and more complex parameters, are not easily visualized and are, therefore, difficult for an average user to routinely modify to accommodate his situation and plans." In the excerpts cited above, applicant has specifically distinguished thresholds based upon a rate of change, such as Shin's first-order derivative threshold, or more complex parameters, such as Shin's second-order derivative threshold, with the threshold profiles described in applicant's specification.

Examiner states (page 3, last paragraph) that Shin discloses the use of a continuously fluctuating threshold profile. Applicant respectfully disagrees. While Shin describes varying thresholds in paragraphs 21 and 163, Shin does not describe continuously varying thresholds. Shin does not use the word continuous when describing his thresholds. In Figures 8 and 9 Shin illustrates thresholds (clipping functions) as step functions. Applicant respectfully suggests that the thresholds described by Shin are not continuously varying, but are in fact discontinuous step functions.

The thresholds described by Shin are a function of the current blood glucose value. It is well known in the art that the variance of data is often a function of the magnitude of the data. In paragraph [0021] Shin states: "The first and second thresholds may vary depending on the blood glucose concentration." and in paragraph [0163]: "The predetermined threshold may vary depending on the current level of blood glucose in the patient. The threshold may be a function of the current level of blood glucose in the patient. At higher glucose levels, the glucose level may potentially change at a faster rate

than at lower glucose levels. Thus, at higher glucose levels the threshold may be more negative than it is at lower glucose levels."

In contrast to Shin's glucose-level dependent thresholds the threshold profiles of the application are a function of time and expected blood glucose concentration. In paragraph [0048] applicant states: "The terms 'threshold profile' (TP), 'blood glucose notification threshold profile' and 'blood glucose threshold profile' as used herein mean a pair of functions comprising upper and lower blood glucose notification thresholds as functions of time. The upper and lower BGC notification threshold functions are the upper and lower bounds of an expected BGC range." and in paragraph [0064]: "The upper and lower BGC threshold functions may be defined directly; they may be defined indirectly as functions of an expected BGC function;…"

Finally, Shin's thresholds are being used to accept or reject incoming glucose sensor data, thus the thresholds are a function of current incoming data. Thus in paragraph [0025] Shin states: "…threshold may vary depending on a current plurality of data values." and in paragraph [0162]: "…the first-order derivative calculation can be based on the final glucose value reading…" and in paragraph [0163]: "…may vary depending on the current level of blood glucose…" and "The threshold may be a function of the current level of blood glucose…" Examiner notes, in the last paragraph on page 3 of the office action, "that if the threshold can vary based upon the current glucose level it will continuously fluctuate along with a changing glucose concentration." However applicant's threshold profiles do not change in response to current glucose level or changing glucose concentration, they are instead based upon expected blood glucose concentration behavior.

As shown in Figures 1-12 of applicant's specification and as described in paragraphs 0048,0064, 0066, 0067, 0086, 0089, 0091, and elsewhere, applicant's threshold profiles are based upon expected blood glucose concentrations, not current blood glucose values as described by Shin. Current blood glucose measurements are compared to expected blood glucose notification threshold profiles to see if deviations from expected behavior are occurring.

The Manual of Patenting Examination Procedure, Section 2141, Part III states that objective evidence of non-obviousness must be considered including: "failure of others, copying by others." Shin and Saidara have both assigned their patent applications to Medtronic MiniMed Inc., and since both Shin and Saidara reside in the Los Angeles, CA area, it is reasonable to assume that they work together, or are at least aware of one another's work. Applicant respectfully suggests that if it was obvious to combine the teachings of Shin and Saidara they would have done so, and that their failure to combine their teachings constitutes objective evidence of non-obviousness of the applicant's invention, particularly in light of Medtronic's heavy patenting activity in art of glucose monitors.

Finally, applicant has noticed copying by others. Applicant's PCT application, corresponding to the instant application, published on December 14, 2006 (WO 2006/133348). The application of Steil (US 2008/0183060), who has assigned his application to Medtronic MiniMed Inc. was filed January 31, 2007. The application describes a semi-closed loop system in which historical meal and insulin data, current data, and a model are used to generate a predicted BGC curve. The user is then asked to approve the predicted BGC curve. Once approved, the system informs the user if BGC

evolves differently from the prediction. This is essentially continuous glucose monitoring with fluctuating BGC thresholds. In addition, Bengtsson (WO 2008/135329), filed July 4, 2008, describes insulin advisory algorithms. Fluctuating BGC thresholds are mentioned as dynamic safety limits (page 6, lines 19-20, also Figure 3).

In response to Examiner's suggestions claims 1 and 25 have been amended to include the elements of:

the threshold functions comprising functions of expected blood glucose concentration as a function of time;

the threshold functions comprising the bounds of an expected blood glucose concentration range;

Support for these elements may be found in paragraph [0048] of the specification.

In response to Examiner's suggestion claim 13 has been amended to include the element of a processor. Support for the element may be found in US 2005/0038332 which was incorporated by referenced in paragraph [0008] of applicant's specification. Further support for the element may be found in paragraph [0118].

Applicant respectfully requests that the rejections be withdrawn and that a timely Notice of Allowance be issued in this application.

Sincerely,

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